

REMARKS

Claims 124-130 and 143-149 are pending in the application. None of the claims are amended. Applicants provide a clean set of the claims for the examiner's convenience. The office action is discussed below:

Response to Arguments and Anticipation Rejection:

On pages 2-7 of the Office Action, the examiner states that the arguments, filed on November 19, 2009, are not persuasive and maintains the rejection.

Applicants respectfully disagree with the examiner and traverse the rejection. Applicants submit that the examiner has repeated almost the same response (see pages 2-5 of the instant Office Action) as the Office Action of April 10, 2008 (see pages 2-5) and May 19, 2009 (see pages 2-5).

With respect to inherent functions or properties in a disclosure the examiner refers to the same passage (see the Office Action of April 10, 2008 or May 19, 2009) from the MPEP that: "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient".

On page 2 of the current Office Action, the examiner alleges that the applicant has not provided any evidence to support the argument that it is inherent that UHMWPE is heated to melt after each passage through the conveyor belt of a van de Graaff generator and that several irradiation passes and heating steps are inherent to the method disclosed in Example 6. Applicants disagree with the examiner and point out to the clarifications (see pages 8-9 of the response filed on November 19, 2009) and evidences (Exhibits 1-4) provided with the response filed on November 19, 2009, which also include exhibits of the generator used in "Example 6". It was further clarified that it is inherent that UHMWPE is heated to melt after each passage through the conveyor belt of a van de Graaff generator, and that several irradiation passes and heating steps are inherent to the method disclosed in Example 6 of the original

specification.

On page 2 of the Office Action, the examiner states Example 6 does not mention a conveyor belt, cycles of radiation or heating the UHMWPE sample to melt after each passage though a conveyor belt to apply radiation. On the contrary, on page 3 of the Office Action, the examiner admits that a conveyor belt is shown and that irradiation would be performed in multiple doses to reach 20 Mrads if the conveyor belt were employed. This clearly shows that the examiner has failed to understand the irradiation process while it is evident from the exhibits that samples are placed on the conveyor belt in order to run through the radiation beam.

The examiner also contends that this is not persuasive with respect to the instant claim recitations, i.e., irradiating a fabricated article comprising UHMWPE, melting the irradiated UHMWPE, allowing the crosslinked UHMWPE to cool, and forming an implant for the crosslinked UHMWPE.

Again, regarding the extrinsic evidence to establish the inherency and to make it clear that the missing descriptive matter is present in the thing described in the reference, applicants submit that the specification provide full support regarding the inherent disclosure and the declarations as discussed previously further provide extrinsic evidence to establish the inherency of the claimed process steps, as are clear to one skilled in the art who are familiar with the van de Graaff generator. See Example 6 at pages 44-46, for example, although the thermal treatment was continued through the irradiation process of cross-linking, it is inherent that the UHMWPE is heated to melt after each passage through the conveyor belt, that is, after each cycle of irradiation, which includes heating in between two "melting" (that is, before and after each irradiation dose or a total dose of irradiation). Thus, it would be apparent to one skilled in the art reviewing the present specification and to those who is familiar with van de Graaff generator that specimens are taken out of the belt and reintroduced to continue on the irradiation process to achieve the desired total dose (in this case a total of 20 Mrad at a dose rate of 2.5 Mrad per pass, for example). It also would be apparent to one skilled artisan that after each passage the UHMWPE is taken out of the belt and melted when reintroduced to the belt to continue on heating (to melt) and irradiation

cycle till the desired total dose is achieved. Applicants refer to the examiner's understanding in a related case that the irradiation was applied in a sequential manner in view of Dr. Muratoglu's declaration (see declaration at section 6, filed July 16, 2008 in US 11/006,786, copy provided with the response filed on November 19, 2009) that clarifies a sequential process for preparing a medical implant by irradiating polymeric material, heating the irradiated polymer and cooling the radiation cross-linked material. The declaration thus provides extrinsic evidence to make it clear that the missing descriptive matter would be so recognized by persons of ordinary skill who are familiar with van de Graaff generator.

Therefore, the inherency of the claimed process was not established by "probabilities or possibilities" nor based on the mere fact that a certain thing may result from a given set of circumstances, as alleged by the examiner. In fact, it is clear to one skilled in the art, who is familiar with van de Graaff generator, that the recited steps are inherent to the claimed process as disclosed in the original specification.

Furthermore, regarding the inherent features of the process steps, as recited in the claims, in the absence of evidence to support such inherent features, for example, based on use of a van de Graaff generator, applicants invite the examiner to consider the MPEP that states:

"The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

See MPEP §2163.02, Rev. 6, September 2007 at 2100-186.

Applicants submit that what is known in the field and accessible to all need not be repeated in the specification. *Falkner v. Inglis*, 448 F.3d 1357, 1365-68, 79 USPQ2d 1008 (Fed Cir. 2006).

As clarified previously and as evident from the declaration (see declaration at section 6, filed July 16, 2008 in US 11/006,786; copy provided with the response filed on November 19, 2009), applicants also submit that the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicants were in possession of the invention as now claimed. Thus, it is not necessary that the claimed subject matter be described verbatim in the specification.

Applicants submit, as discussed above that the detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. In this context, applicants refer the examiner to the MPEP that states:

"The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement...."

See MPEP §2163.02, Rev. 6, September 2007 at 2100-186.

Applicants also draw the examiner's attention to the following section of the MPEP §2163.07(a) (Eighth Edition, Rev. 6, September 2007 at 2100-192) that dictates:

"By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971), *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973)."

In order to assist the examiner in understanding the methods, as recited in the claims, and the irradiation process using the van de Graaff generator, applicants herewith submit a declaration of Dr. Orhun Muratoglu further explaining the process that one skilled in the art would understand the inherency of the claimed process steps.

Applicants refer to sections 5-8 of Dr. Muratoglu's declaration and the Exhibits 1-

3 enclosed therewith, which identifies the conveyor belt that is used to move samples to pass under the e-beam of energetic electrons. It is explained in the declaration that for irradiation by electrons, the samples are carried by the conveyor belt under the constant 'shower' beam of energetic electrons provided by the generator. The amount of total dose desired is used to determine the intensity of the electron beam, and also the number of passes under the beam if more than one passes are required for higher levels of total dose.

For example if a total dose of 25 kGy was to be delivered to a sample, it could be done with a single high intensity pass of 25 kGy/pass, or it might be done with 2 passes of 12.5 kGy/pass, or perhaps with 5 passes of 5 kGy/pass, or 10 passes of 2.5 kGy/pass. For 100 kGy dose one could use 4 passes of 25 kGy/pass. Thus, the total dose is the additive sum of the dose per pass accumulated over the number of passes.

Dr. Muratoglu also clarified, in order to obtain a desired total dose multiple passes may be required, which can be accomplished by reversing the direction of the conveyor, or alternately shutting the machine off going into the irradiation shielded room and physically moving the sample to the starting point again, closing the room, starting the machine and again running the conveyor in the same direction for each pass.

Dr. Muratoglu further clarified that the van de Graaff generator used in the claimed process involves:

- A conveyor belt.
- Cycles of radiation necessary to obtain a total dose, that is, the e-beam radiation ceases when the specimen is outside the 'shower' beam of energetic electrons generated by the van de Graaff generator. The sample receives no radiation dose when it is outside of the e-beam radiation station and continues to move on the conveyer belt until it is put back on the belt or the direction of the belt movement is reversed for a second dose. The process is repeated, as discussed above, for example to obtain a total dose of 5 Mrad or more, because the van de Graaff generator provides a dose of 2.5 Mrad per pass in the captioned application. The van de Graaff generator can also be adjusted to deliver

higher or lower radiation doses per pass. It should be therefore clear to the skilled persons and lay persons alike from the sketches (see Exhibits 1 and 2 of Dr. Muratoglu's declaration) that there is a pause or the radiation ceases when sample passes out of the radiation zone and the steps of radiation and ceasing radiation are repeated.

- If the process requires, heating can be continued after each dose of radiation until the desired total dose is received.
- Heating to melt after passages through the conveyor belt also can be done if the radiation is carried out on a heated specimen.
- In any case, the specimens must be taken out of the conveyor belt or out of the radiation "shower" zone and reintroduced to continue on the irradiation process by placing the specimen to the starting point or by reversing the direction of the conveyor belt.
- The irradiation can be performed while the specimen is moving on a belt when multiple doses are necessary to achieve a total absorbed dose (for example 25 MRads).
- If the process requires, the specimen is cooled to room temperature when taken out of the belt or out of the "shower" beam in between the doses.
- If the process requires, the specimens can be taken out of a belt to continue on heating to re-melt when reintroduced to the belt to continue irradiation and heating.

As clarified by Dr. Muratoglu, if a van de Graaff generator is disclosed, one skilled in the art would understand the inherent disclosure of:

- a conveyor belt;
- cycles of radiation;
- ceasing of radiation in between doses until a total desired doses is achieved;
- heating and/or cooling as necessary after passages through a conveyor belt; and
- even if it is not spelled out that the specimens are taken out of the

conveyor belt or the electron "shower" beam in between the doses, one skilled in the art would understand that the specimens are taken out of the e-beam "shower" to be reintroduced to continue the irradiation process until the desired radiation dose is attained.

Applicants refer to above clarifications regarding the van de Graaff generator that, one skilled in the art who is familiar with van de Graaff generator would appreciate and understand that the process involves:

- a conveyor belt;
- cycles of radiation necessary to obtain a total dose as described in the specification;
- heating to melt after passages through the conveyor belt if the radiation is carried out on a heated specimen;
- the specimens must be taken out of the conveyor belt and reintroduced to continue on the irradiation process;
- the irradiation is performed while the specimen is moving on a belt when multiple doses are necessary to achieve a total absorbed dose (for example 20 MRads; and
- the specimens needs to be taken out of a belt to continue on heating to re-melt when reintroduced to the belt to continue irradiation and heating.

Applicants also refer to the above clarification and the specification that clearly disclose that the claimed steps are inherently disclosed in the specification by mention of use of a van de Graaff generator to irradiate UHMWPE (see for example, Example 6). To assist the examiner, applicants refer to the sketches of a common van de Graaff generator operation (see Exhibits 1-3 attached to Dr. Muratoglu's declaration). Accordingly, applicants provide extrinsic evidence to support the arguments as filed on April 16, 2009 and November 19, 2009.

On page 4 of the Office Action, the examiner has made contradictory comments. At line 4, the examiner asserts that "wherein irradiated UHMWPE is subsequently melted, as set forth in the instant claims", whereas at line 14 the examiner states that "None of the instant claims recites "subsequent melting"."

As explained above, irradiation and subsequent heating above the melting temperature and cooling thereafter are inherent in the claimed process.

The examiner also asserts on page 4 of the Office Action that there is no recitation of a "first step" of melting UHMWPE before the step of irradiation and "the step of heating" at 150°C or above or of following the recited heating step with "another irradiation step" and "another heating step" before cooling and forming a medical implant. Again, applicants clarify that claims do not recite the repeated steps of radiation and heating that were required to attain the desired total radiation dose. However, as evident and as clarified above and in the declaration, it is inherent that multiple steps of irradiation and subsequent heating at 150°C or above and cooling are required. Applicants submit that one skilled in the art would understand the process and the inherent multiple steps required in order to obtain the desired product.

Therefore, as stated in the Declaration of Merrill *et al.* (filed on November 19, 2009), Experiment 2 in Exhibit 3 provides the evidence of reduction to practice of the claimed method, including heating of the irradiated materials at 150°C or above and cooling thereafter, before January 20, 1995.

In view of the above clarifications, applicants request withdrawal of the rejection.

Claim Interpretation and Effective Filing Date:

On page 5 of the Office Action, the examiner has reiterated that claims 124-130 and 143-149 recite that the irradiation and subsequent melting method ("IR-SM") first disclosed in SN 08/726,313, filed October 2, 1996, and opined that claims 124-130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of October 2, 1996, and February 13, 1996, which is the filing date of the priority application SN 08/600,744. Therefore, the examiner considers that the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the October 2, 1996 filing date of SN 08/726,313. Applicants respectfully disagree with the examiner and traverse the rejection. Applicants submit the examiner has repeated almost the same responses (see pages 5-6 of the Office Action of April 10, 2008 and page 5 of the Office Action of

May 19, 2009) and has not responded to the clarifications provided in the response filed on April 16, 2009 and November 19, 2009, nor has addressed the declarations discussed therein.

Applicants also submit, as discussed above and as evidenced by the declaration and the Exhibits, that the instantly claimed embodiment, wherein heating of the irradiated materials at 150°C or above and cooling thereafter, was reduced to practice prior to January 20, 1995.

Regarding the priority claim, applicants request the examiner to consider the Rule 1.131 Declaration of Merrill *et al.*, filed June 8, 2007, in a related case U.S. App. No. 10/696,362 (MERRILL *et al.*, copy provided with the response filed on November 19, 2009). In the declaration Professor Merrill clarified that the polyethylene is first melted and then irradiated, which provides the evidence of reduction to practice of a method wherein irradiation is followed by subsequent melting or re-melting. Applicants refer the examiner to the evidence in the Declaration of Merrill *et al.*, filed June 8, 2007 under Rule 1.131, which the examiner has agreed (see Office Action of September 7, 2007, page 2, in the US application serial no. 10/696,362), that the evidence presented shows reduction to practice of the instantly claimed methods before January 20, 1995 (see the Declaration of Merrill *et al.*, sections 10-11 and item b of Exhibit 1, for example), which sufficiently provides the evidence of reduction to practice of the claimed method that involves heating of the irradiated materials at 150°C or above and cooling thereafter.

On page 5 of the Office Action, the examiner also asserts that claims 128-129 are not supported by the disclosure of SN 08/600,744, does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE, thus, according to the examiner claims 128-129 are not entitled to the February 13, 1996. Applicants disagree and refer to the original specification, see for example, Example 4, Tables 2 and 6; and Example 11, Tables 8 and 11 for support.

In view of the above clarifications, applicants submit that Shen *et al.* (the '900 patent) and Hyon *et al.* (the '626 patent), are not prior art to the claimed invention. Accordingly, withdrawal of the anticipation rejection is solicited.

Double Patenting Rejections:

On pages 7-9 of the office action, the examiner has maintained the provisional obviousness-type double patenting rejection of the claims and alleged as being directed to the same invention as the claims of co-pending application serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089, and 10/197,263.

Applicants reiterate, since a notice of allowability has not been issued for any of the application serial nos. 10/948,440, 10/197,209, 10/696,362, and 10/197,263, the merits of this provisional rejection need not be discussed with the examiner at this time. See MPEP § 822.01. More specifically, in this context, applicants refer the examiner to the MPEP § 804 I.B. that states:

B. Between Copending Applications-Provisional Rejections

Occasionally, the examiner becomes aware of two copending applications that were filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee, or that claim an invention resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3), that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

Accordingly, the provisional double-patenting rejection over the co-pending application serial nos. 10/948,440, 10/197,209, 10/696,362, and 10/197,263 should be withdrawn.

With respect to the recently allowed application serial no. 10/901,089 (the '089 application, now U.S. Patent No. 7,858,671), applicants submit that the issued claims are substantially different from the instant claims. Of the alleged claims 124-129 of the '089 application, claims 124-127 and 129 have been cancelled. The extensively amended claim 128 and none of the other independent claims recite heating of the irradiated UHMWPE to a temperature of 150°C or above, as required by the claimed methods. Accordingly, the instant claims are patentably distinct from the claims of the '089 application. Therefore, the obviousness-type double patenting rejection in view of the '089 application should be withdrawn.

REQUEST

Applicants submit that claims 124-130 and 143-149 are in condition for allowance, and respectfully request favorable consideration to that effect so that an interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at (202) 628-6600 should there be any questions.

Respectfully submitted,



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